K102579
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510(k) Summary of Safety & Effectiveness

DEC - 2 2010

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1. (a)	**Submitter Address:**	George J. Hattub MedicSense, USA 291 Hillside Avenue Somerset, MA 02726 www.medicsense.com
1. (b)	***Manufacturer Address:***	Biological Signal Processing Ltd. 22a Raul Wallenberg Street Tel-Aviv 69719, Israel
	Mfg. Phone:	Tel.: 972-3-647-4840
	Contact Person:	Eran Toledo
	Date:	August 31, 2010
2.	***Device & Classification Name:***	Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms) device as a class II device (product code MWI, 21 CFR 870.2300) HyperQ™ AD-100 System
3.	***Predicate Device:***	HyperQ™ System K082564
4.	***Description:***	The HyperQ™ AD-100 System is a compact monitor for measuring, processing, storing, and displaying information derived from an electrocardiogram (ECG). The device analyzes and records the high frequency components of the QRS complex of standard ECG.
5.	***Intended Use:***	ECG ECG is intended to disclose either normal condition or patterns of arrhythmia, myocardial ischemia, rate abnormalities, or features of prognostic value in the following cases: Patients with suspected cardiac abnormalities Populations of patients at an age or period in which a routine baseline evaluation of ECG characteristics is desired. Stress Testing Angina pectoris (chest pain) is a clinical syndrome resulting from myocardial ischemia, indicative of reduced blood supply to the cardiac muscle. The electrocardiogram may establish the diagnosis of ischemic heart disease if characteristic changes are present. Stress testing is the most widely used method to decide whether this chest

pain is related to myocardial ischemia, and thus to coronary artery disease. In stress testing, the contractile capability of the heart muscle is monitored via ECG during patient exercise. Patients exercise by bicycle, treadmill, or other means, while the ECG is monitored continuously. Exercise loads are determined by predefined protocols. The ECG signals as well as the HF-QRS signals are recorded for the resting, exercise, and recovery phase portions of the exercise protocol. The changes in both ECG waveforms are compared to the resting ECG records. In the HyperQ™ stress test, changes in the high frequency of the mid QRS complex, calculated as root-mean-square (RMS) values, are compared to the resting values.
Most of the commercial stress test systems control the bicycle or treadmill automatically according to the requirements of the chosen protocol, although this is not essential.

ST segment monitoring is intended as an aid in the evaluation of myocardial ischemia in patients with known or suspected coronary artery disease. The ST segment algorithm has been tested for accuracy of the ST segment data, and a database is used as a tool for performance testing.
The significance of the ST segment changes must be determined by a physician.

HyperQ™
The HyperQ™ Software is intended to be used as an aid to stress ECG test by means of analysis of high frequency components present within the central portion of the QRS complex.

The significance of the HF-QRS changes must be determined by a physician.

6. ***Comparison of Technological Characteristics:***

With respect to technology and intended use, the Modified HyperQ™ System (HyperQ™ AD-100 System) is substantially equivalent to its predicate device which is the HyperQ™ System. The primary difference is that the modified device has the ability to be an accessory (add-on) to a legally marketed ECG Stress System to provide HyperQ analysis from the acquired ECG. Based upon the validation results, BSP believes this change does not raise additional safety of efficacy concerns. In addition, the system has passed IEC Electrical Safety Testing as well as EMC.

The following predicate comparison table delinerates the specific similarities and differences:

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Characteristic	Predicate Device (System)	Modified Device (System)
Number of Electrodes	10	same
Number of Leads	12	same
ECG Samples/second	1000	same
A/D Bits	16 (0.15 µVLSB)	same
Defibrillation Protection	Built In	same (utilizes a defibrillation proof patient cable)
Input Signal dynamic range	10 mV	same
Simultaneously 12L	Yes, with sample/hold circuitry to assure zero delay between leads	same
CMMR	> 100 dB	same
Input Impedance	> 100M Ohm	same
DC max input	±330 mV	same
Frequency Range (-3db)	0.05-300 Hz	same
Low pass filter (software)	35 Hz	same
Line pass filter (software)	50/60 Hz	same
Safety Standard	IEC 60601-1, EN 60601-2, IEC 60601-2-25, IEC 60601-2-27, EC11 ST Segment Analysis EC 38-1999	Same
Operating Temperature	0°C to 50°C	same
Treadmill Control	yes	no
On Line ECG	yes	no
HyperQ calculated from on line ECG	yes	yes
Power	5 V	same
Current	80 mA	200 mA
Dimensions	15 x 12 x 2 cm	17 x 11 x 2.5 cm
Weight	200 grams	same
Storing Temperature	-20°C to 60°C	same
Humidity	0-85%	same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Biological Signal Processing, Ltd.
c/o Mr. George J. Hattub
Senior Staff Consultant
MedicSense, USA
291 Hillside Avenue
Somerset, MA 02726

DEC - 2 2010

Re: K102579
Trade/Device Name: Hyper-Q™ AD-100 System
Regulatory Number: 21 CFR 870.2300
Regulation Name: Patient Physiological Monitor (without arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: 74 MWI
Dated: October 26, 2010
Received: November 2, 2010

Dear Mr. Hattub:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

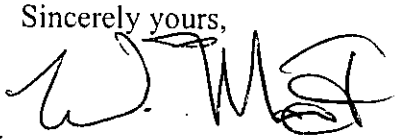
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102579

Indications for Use

510(k) Number (if known): DEC - 2 2010

Device Name: HyperQ™System

Indications For Use: ECG is intended to disclose either normal condition or patterns of arrhythmia, myocardial ischemia, rate abnormalities, or features of prognostic value in the following cases:
- Patients with suspected cardiac abnormalities
- Populations of patients at an age or period in which a routine baseline evaluation of ECG characteristics is desired.

Stress Testing

Angina pectoris (chest pain) is a clinical syndrome resulting from myocardial ischemia, indicative of reduced blood supply to the cardiac muscle. The electrocardiogram may establish the diagnosis of ischemic heart disease if characteristic changes are present.
Stress testing is the most widely used method to decide whether this chest pain is related to myocardial ischemia, and thus to coronary artery disease. In stress testing, the contractile capability of the heart muscle is monitored via ECG during patient exercise. Patients exercise by bicycle, treadmill, or other means, while the ECG is monitored continuously. Exercise loads are determined by predefined protocols. The ECG signals as well as the HF-QRS signals are recorded for the resting, exercise, and recovery phase portions of the exercise protocol. The changes in both ECG waveforms are compared to the resting ECG records. In the HyperQ™ stress test, changes in the high frequency of the mid QRS complex, calculated as root-mean-square (RMS) values, are compared to the resting values.

Most of the commercial stress test systems control the bicycle or treadmill automatically according to the requirements of the chosen protocol, although this is not essential.

ST segment monitoring is intended as an aid in the evaluation of myocardial ischemia in patients with known or suspected coronary artery disease. The ST segment algorithm has been tested for accuracy of the ST segment data, and a database is used as a tool for performance testing.

The significance of the ST segment changes must be determined by a physician.

HyperQ™

The HyperQ™ Software is intended to be used as an aid to the ECG stress test by means of analysis of high frequency components present within the central portion of the QRS complex.

The significance of the HF-QRS changes **must** be determined by a physician.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102579